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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,705	06/01/2001	William J. Roberts	1400-002	2502
33461	7590	06/29/2004	EXAMINER	
SULLIVAN LAW GROUP 1850 NORTH CENTRAL AVENUE SUITE 1140 PHOENIX, AZ 85004			QAZI, SABIHA NAIM	
			ART UNIT	PAPER NUMBER
			1616	
DATE MAILED: 06/29/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/872,705	<b>Applicant(s)</b> ROBERTS, WILLIAM J.	
	<b>Examiner</b> Sabiha N. Qazi	<b>Art Unit</b> 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 3-7, 11-13 and 29-233 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1, 2, 8-10, 14, 22-28, 34-37 and 49-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 3-7, 11-13 and 29-233 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Non-Final office Action***

Acknowledgement is made of the response filed on 3/23/04. Amendments are entered. Claims 1-61 are pending. Claims 1, 2, 8-10, 14, 22-28, 34-37 and 49-61 are rejected others are withdrawn from consideration as non-elected invention. Rejection under 112 is withdrawn in part because arguments are found persuasive. Rejection of promoiety is maintained for the same reason as set forth in our previous office action. Applicants need to explain methoxymethyl ether in the rejected claims. Rejection will be withdrawn when the arguments would be found persuasive.

Presently claimed invention is drawn to a compound for supplementing the concentration of parent androgen as in claim 1.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

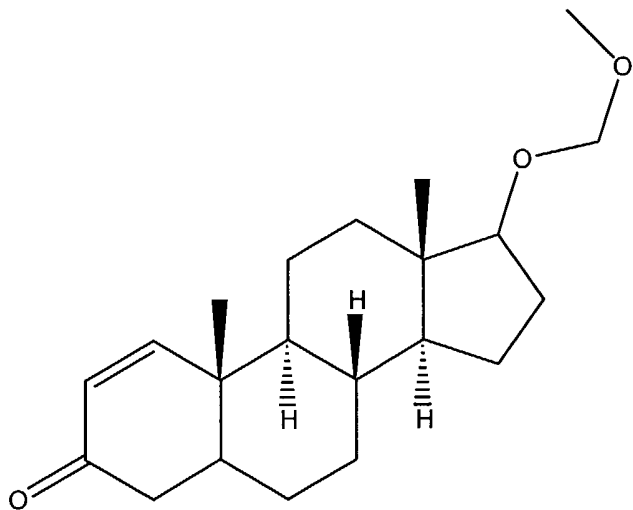
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 2, 8-10, 14, 22-28, 34-37 41 and 49-61 are rejected under 35 U.S.C. 112, second paragraph, is maintained (in-part).

2. Compounds claimed in claims 16-21 does not contain alkoxymethyether at 17-position. Structures are drawn to make the difference clear. Therefore they are improperly dependent on claim 1.

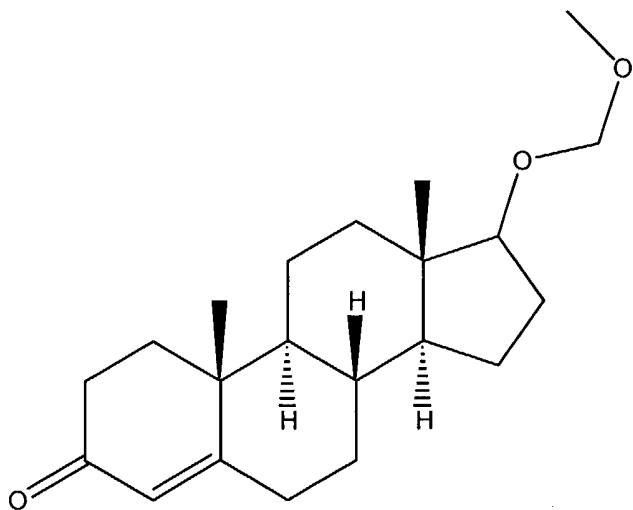
3. What is intended by a "promoiety comprising".

1. (Claim 13)



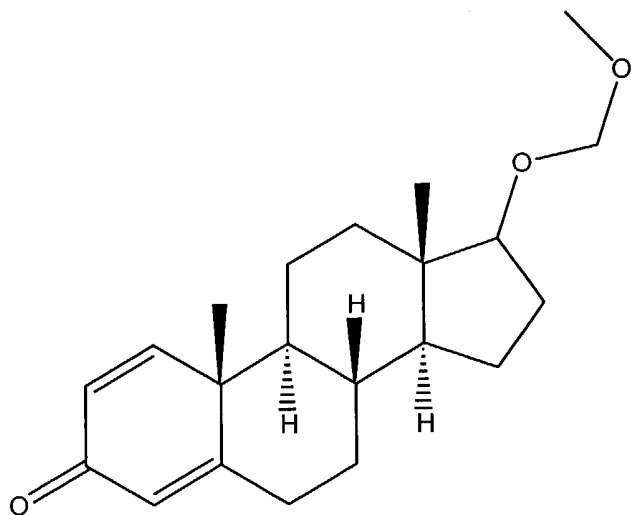
17-methoxymethoxyandrost-1-ene-3-one

2. (Claim 14)



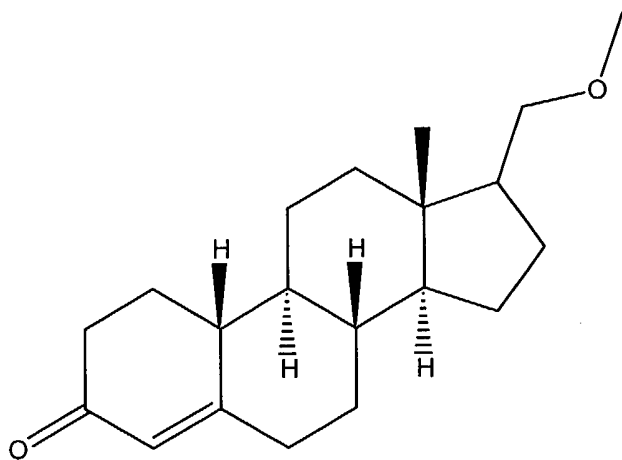
17-methoxymethoxyandrost-4-ene-3-one

3. (Claim 15)



17-methoxymethoxyandrost-1,4-diene-3-one

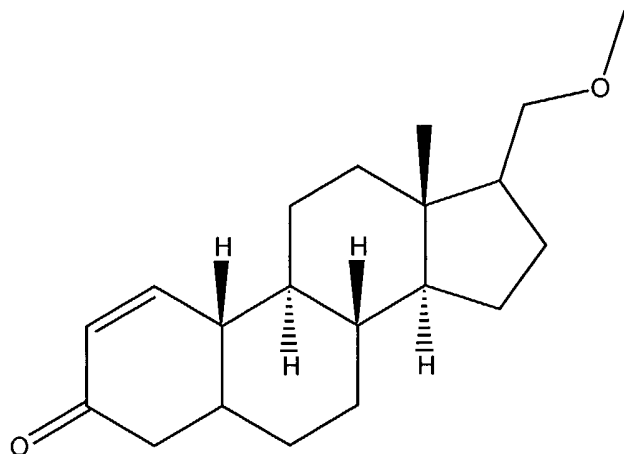
4. (Claim 17)



17-methoxymethylestra-4-ene-3-one

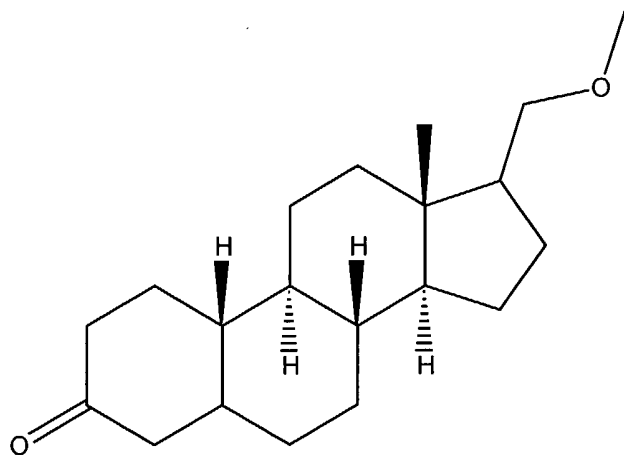
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5. (Claim 16)



17-methoxymethylestra-1-ene-3-one

6. (Claim 21)



17-methoxymethylestran-3-one

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1,2 8-10, 14, 22-28, 34-37, 41 and 49-61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 59-74 of copending Application No. 10/054505. Although the conflicting claims are not identical, they are not patentably distinct from each other because presently claimed invention is drawn to a composition for supplementing the concentration of a parent androgen in a subject in vivo when the parent androgen is 17-hydroxy-androstan-1-ene-3-one.
3. Claims of 10/053505 are drawn to a composition for increasing the concentration of a parent androgen in a subject in vivo, when the androgen is androgen-4-ene-3a, 17b diol.
4. Since the androgen differs at 3-position having OH vs C=O, which when given to a subject will serve the same purpose that is supplementing or increasing the concentration of the said androgen. For the same reasons presently claimed invention is considered obvious over the claims of related application 10/053505.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


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***Communication***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is 703-305-3910. The examiner can normally be reached on every business day..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
SABIHA QAZI, PH.D  
PRIMARY EXAMINER

SABIHA QAZI, PH.D  
PRIMARY EXAMINER